Paper No. 37

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

_____

Ex parte GLENN J. GORMLEY
and ELIZABETH STONER

_____

Appeal No. 1997-2801
Application 08/364,072

_____

ON BRIEF

_____

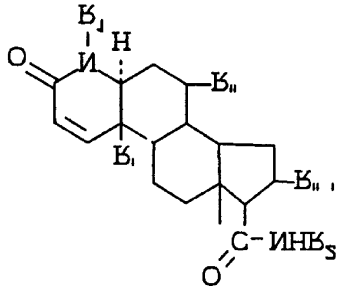
Before WINTERS, WILLIAM F. SMITH, and LORIN, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1 through 8, all the claims remaining in the application, which read as follows:

1. A method of preventing prostatic carcinoma in humans, who are asymptomatic for prostatic cancer, which comprises of daily administering a therapeutically effective amount of a compound of the formula:



wherein:

R^1 is hydrogen, methyl or ethyl;

R^2 is a hydrocarbon radical selected from straight or branched chain alkyl, cycloalkyl, or aralkyl of from 1-12 carbons or monocyclic aryl optionally containing 1 or more lower alkyl substituents of from 1-2 carbon atoms or 1 or more halogen (Cl, F or Br) substituents;

R' is hydrogen or methyl;

R" is hydrogen or $-methyl;

R"' is hydrogen, "-methyl or $-methyl.

2. A method according to Claim 1 wherein:
R^1 is hydrogen or methyl;
R^2 is a branched chain alkyl of from 4-8 carbon atoms;
R', R", R"' are hydrogen.

3. A method according to Claim 1 wherein the compounds are:

17$-(N-tert-butylcarbamoyl)-4-aza-4-methyl-5"-androst-1-en-3-one;
17$-(N-tert-butylcarbamoyl)-4-aza-5"-androst-1-en-3-one;
17$-(N-isobutylcarbamoyl)-4-aza-4-methyl-5"-androst-1-en-3-one;
17$-(N-isobutylcarbamoyl)-4-aza-5"-androst-1-en-3-one;
17$-(N-tert-octylcarbamoyl)-4-aza-4-methyl-5"-androst-1-en-3-one;
17$-(N-tert-octylcarbamoyl)-4-aza-5"-androst-1-en-3-one;

17$-(N-1,1-diethylbutylcarbamoyl)-4-aza-4-methyl-5"-androst-1-en-3-one;
17$-(N-1,1-diethylbutylcarbamoyl)-4-aza-5"-androst-1-en-3-one;
17$-(N-tert-hexylcarbamoyl)-4-aza-4-methyl-5"-androst-1-en-3-one;
17$-(N-tert-hexylcarbamoyl)-4-aza-5"-androst-1-en-3-one;
17$-(N-2-adamantylcarbamoyl)-4-aza-5"-androst-1-en-3-one,
17$-(N-1-adamantylcarbamoyl)-4-aza-5"-androst-1-en-3-one,
17$-(N-2-norbornylcarbamoyl)-4-aza-5"-androst-1-en-3-one, or
17$-(N-1-norbornylcarbamoyl)-4-aza-5"-androst-1-en-3-one,[.][1]

4. A method according to Claim 3 wherein the compound is 17$-(N-tertbutylcarbamoyl)-4-aza-5"-androst-1-en-3-one.

The examiner relied on the following reference:

Johnson	5,300,294	Apr. 5, 1994 (filed Jun. 27, 1990)

The references relied upon by this merits panel are:

Rasmusson et al. (Rasmusson)	4,760,071	Jul. 26, 1988
Eur. Pat. App. (EP'383)	0 285 383	Oct. 5, 1988

Illustrated Stedman's Medical Dictionary (Stedman), 24th Edition, Williams & Wilkins, Baltimore (1982), pp. 675-677.

Claims 1 through 8 stand rejected under 35 U.S.C. § 103. The examiner relies upon Johnson as evidence of obviousness. Claims 1 through 8 stand provisionally rejected under 35 U.S.C. § 101(double patenting) over claims 1 through 8 of copending application Serial No. 08/104,964. We reverse the section 103 rejection. The double

[1] The record copy of claim 3 does not have a terminal period.

patenting rejection is moot. In addition, we make two new grounds of rejection under the provisions of 37 CFR § 1.196(b).

Discussion

Obviousness

The claimed subject matter is directed to preventing prostatic carcinoma in humans, who are asymptomatic for prostatic cancer. According to appellants, the term "[a]symptomatic . . . is meant that overt signs of the disease are not present, or indicated, e.g. lumps or cysts on the prostate wall." Specification, page 4, lines 16-19.

Johnson is directed to treating patients that have prostatic adenocarcinoma by administering a therapeutical amount of a steroid 5-"-reductase inhibitor. Johnson discloses that the inhibitor can include 17$-(N-tert-butylcarbamoyl)-4-aza-5"-androst-1-en-3-one, which is the compound recited in appealed claim 4. Johnson, col. 2, lines 21-29; col. 3, lines 5-6. Johnson discloses that the administration of steroid 5-"-reductase inhibitor decreases the size of prostate tumors. Johnson, col. 3, lines 66-68. The patients in Johnson do not meet the claim limitation "asymptomatic for prostatic cancer."

The examiner states in the rejection that "one skilled in the art would be motivated to employ the known anti-prostatic adenocarcinoma compounds of the prior to prevent prostatic adenocarcinoma." Answer, page 3, lines 15-19. However, the examiner has not pointed to any specific disclosure in the prior art to support this statement. In response to appellants' arguments, the examiner argues that in the process of treating a patient, "there is a time when the tumors is [sic, are] gone and the patient is still getting the drug . . . the

drug is being employed to prevent the tumor from coming back." Answer, page 4, lines 4-8. However, we find no disclosure in Johnson which supports this statement. To establish a prima facie case of obviousness, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 984, 180 USPQ 580, 582 (CCPA 1974). Here, the examiner has not properly considered the subject matter as whole in reaching his holding of obviousness.

The rejection under 35 U.S.C. § 103 is reversed.

Double Patenting

The PTO records available to us indicate that application 08/104,964 is now abandoned. Accordingly this rejection is moot. In the event of further prosecution, the examiner should determine whether that application has been refiled. If so, the examiner should review the claims pending in such an application and determine whether double patenting issues exist.

The provisional rejection under 35 U.S.C. § 101 is moot.

New Ground of Rejection Under 37 CFR § 1.196(b)

Under the provisions of 37 CFR § 1.196(b) we enter the following new grounds of rejection.

(1) Claims 1 through 8 are rejected under 35 U.S.C. § 102(b). In support of this rejection we rely upon Rasmusson and Stedman.

Rasmusson describes a method of treating patients with benign prostate hypertrophy by administering a therapeutically effective amount of a 17$-N-(monosubstituted)-carbamoyl-4-aza-5"-androst-1-en-3-one compound represented by formula I disclosed by Rasmusson. The compounds described by Rasmusson includes those recited in claim 1 on appeal. For example, Rasmusson discloses that the compound 17$-(N-tert-butylcarbamoyl)-4-aza-5"-androst-1-en-3-one, which is the compound recited in claim 4 on appeal. Rasmusson, col. 2, line 14, to col. 3, line 29; col. 5, lines 67-68. Rasmusson also indicates that the compound can be administered orally at a daily dosage of from 50 to 2,000 mg and that an effective amount of the drug is ordinarily from about 1 mg to about 50 mg/kg of body weight per day, preferably from about 1 mg to 7 mg/kg of body weight per day which are well below the toxic dose of the compound. Rasmusson, col. 6, line 64, to col. 7, lines 12.

Benign prostate hypertrophy (nodular hyperplasia of prostate) is defined as glandular and stromal hyperplasia which occurs very commonly in the middle and lateral lobes of older men, forming nodules that may increasingly obstruct the urethra. Stedman, pages 676 and 677. (Hyperplasia is defined as an increase in the number of cells in a tissue or organ, excluding tumor formation, whereby the bulk of the part or organ is increased. Stedman, page 675.)

Rasmusson teaches that the active agents are to be used to treat benign prostatic hyperplasia without qualification as to whether the patients are symptomatic or asymptomatic for prostatic cancer. To the extent Rasmusson teaches the administration of the active agents to patients who are asymptomatic for prostatic cancer, those patients meet the requirements of the claims on appeal in regard to (1) the persons being treated, (2) the active agent used and (3) the amounts of active agent used. Thus, we hold that Rasmusson describes the claimed subject matter and, therefore, constitutes an anticipation. We recognize that the claims on appeal recite that the purpose of the treatment is to prevent prostatic carcinoma in patients that are asymptomatic for prostatic cancer. However, "[I]t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

(2) Claims 1 through 8 are rejected under 35 U.S.C. § 102(b). In support of this rejection we rely upon EP'383 and Stedman.

EP'383 describes a method of treating patients with benign prostate hypertrophy that comprises administering a therapeutically effective amount of a 17$-N-monosubstituted-carbamoyl-4-aza-5"-androst-1-en-3-one compound of Formula I which is within the scope of the formula recited in claim 1 on appeal. EP'383 also describes that the compound can be 17$-(N-tert-butylcarbamoyl)-4-aza-5"-androst-1-en-3-one as

required by claim 4 on appeal. EP'383, page 2, line 46, to page 3, line 61; page 6, lines 27-28. EP'383 discloses that the compounds of that reference can be administered orally at a daily dosage of from 5 to 2,000 mg. EP'383 discloses that an effective amount of the drug is ordinarily supplied at a dosage level of from about 0.1 mg to about 50 mg/kg of body weight per day, preferably from about 0.1 mg to 7 mg/kg of body weight per day, more preferably from 0.01 mg to 3 mg/kg of body weight per day and that these dosages are well below the toxic dose of the compound. EP'383, page 6, lines 27-41.

The definition of benign prostate hypertrophy in rejection (1) above is incorporated herein by reference.

EP'383 teaches that the active agents are to be used to treat benign prostatic hyperplasia without qualification as to whether the patients are symptomatic or asymptomatic for prostatic cancer. To the extent EP'383 teaches the administration of the active agents to patients who are asymptomatic for prostatic cancer, those patients meet the requirements of the claims on appeal in regard to (1) the persons being treated, (2) the active agent used and (3) the amounts of active agent used. Thus, we hold that EP'383 describes the claimed subject matter and, therefore, constitutes an anticipation. We again recognize that EP'383 does not administer the active agent for the purpose of preventing prostatic carcinoma in patients that are asymptomatic for prostatic cancer.

However, claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, supra.

Summary

The obviousness rejection is reversed and the double patenting rejection is moot. We have entered two new grounds of rejection of claims 1-8 under the provisions of 37 CFR § 1.196(b).

Time Period For Response

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED; 37 CFR § 1.196(b)

Sherman D. Winters Administrative Patent Judge	)
William F. Smith Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Hubert C. Lorin Administrative Patent Judge	)

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